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VIA ELECTRONIC FILING

Honorable Dennis M. Cavanaugh, U.S.D.J.
United States District Court
U.S. P.O and Courthouse, Room 451
Federal Square - P.O. Box 99
Newark, NJ 07101-0999

**Re: *Eli Lilly and Company v. Actavis Elizabeth LLC et al.,*
Civil Action No. 07-3770 (DMC)(MF) (D.N.J.)**

Dear Judge Cavanaugh,

We, along with our co-counsel Alston & Bird LLP, are counsel for defendant Mylan Pharmaceuticals Inc. ("Mylan") in the above matter. We write to Your Honor jointly on behalf of Mylan as well as Defendants, Apotex, Inc., Aurobindo Pharma Ltd., Sandoz, Inc. and Sun Pharmaceutical Industries Ltd. (collectively "Defendants"). We seek Your Honor's assistance regarding an evidentiary matter that appears to remain open subsequent to the Court's issuance of its recent Opinion regarding the parties' motions *in limine*. For the reasons herein, Defendants respectfully submit that the subject evidence is barred by the law of the case, among other reasons.

On May 5, Magistrate Judge Falk had granted Lilly's request to permit Dr. Steven M. Paul to testify as a fact witness at trial (Dkt. 575). That motion and Defendants' opposition (Dkt. 592) were considered and heard by Magistrate Judge Falk, who issued his opinion regarding the same (Dkt. No. 618). As part of Defendants' opposition, we raised several *in limine* evidentiary challenges regarding the subject matter of Lilly's proffered testimony of Dr. Paul ("Lilly's Proffer").¹

¹ The subject matter of Lilly's Proffer is directed to the so-called significance of the Internal Review Board of Massachusetts General Hospital's ("MGH") approval of the clinical tests set forth in IND 46,806. Lilly sought to rely upon this opinion testimony, and related documents, to support its claim that the '590 Patent established a credible utility.

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Notwithstanding that Lilly has now withdrawn Dr. Paul from its witness list, only days after Magistrate Judge Falk ordered his deposition, Lilly has recently asserted that it still intends to offer the subject matter of the Proffer in evidence through other fact witnesses.

As a result of Your Honor's prior ruling that pre-filing approval of the IND clinical studies are irrelevant (See Dkt. 494, pp. 29-30), the law of the case bars Lilly's Proffer, which is also barred by the additional evidentiary challenges raised in Defendants' opposition. Accordingly, we submit that, in light of Lilly's insistence in intending to offer the subject matter of its Proffer in evidence during the trial through other fact witnesses, Defendants *in limine* challenges to that evidence and its request for exclusion thereof remain open. Defendants respectfully request that Your Honor resolve this issue in advance of trial.

Background

Just weeks before the commencement of trial, a dispute arose concerning Lilly's untimely disclosure of Dr. Steven M. Paul as a fact witness. At the final pretrial conference held on April 19, 2010, Magistrate Judge Falk ordered Lilly to make a detailed proffer of Dr. Paul's anticipated testimony. See Plaintiff's Motion *In Limine* to Deny Defendants' Request to Exclude Dr. Steven M. Paul at Trial ("Lilly's Motion") (Dkt. 575). Defendants opposed Lilly's motion on several procedural and evidentiary grounds, seeking the preclusion of the subject matter of Lilly's Proffer. See Defendants' Brief in Opposition. (Dkt. 592).

One reason Defendants sought the exclusion of the subject matter of Lilly's Proffer, among many others, was because it included opinions and documentary evidence concerning pre-filing approvals of clinical trials to ascertain whether atomoxetine could treat ADHD. See Defendants' Brief, Dkt. No. 592 at 21-23 (citing Amended Opinion, Dkt. No. 494 at 28-30). As Your Honor is aware and as stated in Defendants' opposition, this Court has already determined that pre-filing approvals of clinical trials that were not submitted to PTO, such as the approval of the studies performed pursuant to IND 46,806, could not be used to show utility. See *id.*² Accordingly, Defendants argued that Lilly's Proffer in this regard should be precluded. See *id.*

Magistrate Judge Falk rendered an oral opinion on the record and issued his opinion and order on May 7 (Dkt Nos. 617, 618) directing that Dr. Paul be made available for deposition and Lilly bear all costs and expenses associated therewith. *Id.* at 17. However, Magistrate Judge Falk did not directly rule on Defendants' *in limine* evidentiary challenges regarding Lilly's Proffer, but recognized "what appear to be significant evidentiary obstacles...." to Lilly's Proffer. *Id.* at 17; see also 5/5/10 Hrg. Tr. 93:21-94:2 ("I'm simply going to state my opinion that there would appear to be very serious substantive and evidentiary impediments to the admission of much of the testimony outlined in the proffer...."). Moreover, Judge Falk indicated that

² The Court has similarly upheld the law of the case with respect to post-filing date test data, granting Defendants' motion *in limine* to preclude Plaintiff from introducing post-filing date test data to demonstrate utility. See Dkt. No. 621 at 10-11.

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Defendants' evidentiary challenges were preserved. *See* 5/5/10 Hrg. Tr. 93:20-25; *see also id.* at 81:2-6.

Moments before Magistrate Judge Falk issued his written Opinion, Lilly sent a letter to him withdrawing Dr. Paul as a witness because he was allegedly unavailable for the ordered deposition. *See* Lilly May 7, 2010 Letter to the Court. *Notwithstanding Lilly's withdrawal of Dr. Paul*, Lilly, nonetheless, during a teleconference held with Magistrate Judge Falk on May 11, asserted that it still intended to offer the subject matter of Lilly's Proffer through other Lilly fact witnesses, including Dr. Martin Hynes and Dr. Albert Allen.

Conclusion

In light of Defendants' evidentiary challenges, in particular our reliance upon this Court's prior opinion and law of the case, Defendants respectfully request that Lilly be precluded from offering evidence relating to its Proffer as it encompasses pre-filing approvals of clinical trials in support of Lilly's asserted utility of the alleged invention of the '590 Patent.

We thank the Court for its continued assistance and understanding in this matter and its indulgence in accepting this letter.

Respectfully submitted,


Arnold B. Calmann

cc: All Counsel of Record (via email)